EXHIBIT A

PATENT
Attorney Docket No. 12637/88

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s)	:	MAYBERG, Marc	Customer No. 23838
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Art Unit	:	3762	
Title:	:	BRAINSTEM AND CEREBELLAR MODULATION OF CARDIOVASCULAR RESPONSE AND DISEASE	
Examiner	:	George R. Evanisko	

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Commissioner for Patents
P.O. Box 1450
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DECLARATION OF DR. ANDRE MACHADO UNDER 37 C.F.R. 1.132

I, Andre Machado, M.D., hereby declare as follows:

1. I graduated from medical school at the University of Sao Paulo (Sao Paulo, Brazil) in 1997. I received my training in neurosurgery at the University of Sao Paulo from 1998-2004 and at the Cleveland Clinic (Cleveland, OH) from 2004-2006. I currently hold the position of associate staff neurosurgeon at the Cleveland Clinic (Cleveland, OH), which I have held since February 2006.

2. Deep brain stimulation is approved by the Food & Drug Administration (FDA) for the treatment of Parkinson's disease. The brain circuitry involved in Parkinson's disease includes the motor cortex that sends projections to the striatum, which projects to the subthalamic nucleus which, in turn, controls the activity of the globus pallidus. The globus pallidus modulates the activity of the thalamus, which, in turn, drives function in the motor

cortex.

3. Treatment of Parkinson's disease has been accomplished with deep brain stimulation of the globus pallidus, subthalamic nucleus, and thalamus. Although these three structures are part of the same circuit, the effects of stimulation on each structure are not necessarily the same. Specifically, stimulation of the subthalamic nucleus and globus pallidum can alleviate all cardinal symptoms of Parkinson's disease (tremor, rigidity and bradykinesia). Stimulation of the thalamus, on the other hand, improves essentially tremor without significant benefit on rigidity and bradykinesia. This illustrates that stimulation of different components of a given neurological system may generate different results and outcomes.

5. Another example to illustrate this phenomenon is the differential success in outcomes of spinal cord stimulation and thalamic stimulation for refractory neuropathic pain. Based on a current theory on pain physiology, the activation of large diameter fiber pathways in the spinal cord could shut pain transmission. The signals from such activation are thought to be integrated in the dorsal horn and then transmitted to the thalamus. The thalamus relay the information to the cerebral cortex where the pain signal gains consciousness. Based on this theory, it was proposed in the late1960s that stimulation of the large diameter fibers pathway in the spinal cord would enhance the activity of this component of the circuitry and consequently reduce pain perception.

6. Since, as mentioned above, the signals from activation of the large diameter fibers in the spinal cord are integrated in the thalamus, the same rationale was also applied for stimulation of the thalamus. However, only spinal cord stimulation remains a standard of care and well- accepted treatment for long-term pain management. Thalamic stimulation was initially evaluated with enthusiasm but controlled trials failed to show good long-term results and it is not currently approved by the FDA for the management of chronic pain.

7. Operating on the hindbrain carries high risk since the hindbrain functions collectively to support vital bodily processes, such as breathing, swallowing, eye movement,

hearing, blood circulation, heart beat, muscle tone, body movement and equilibrium.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 9.13.06 Signed _____

Andre Machado, M.D.